

In the Application of
Robert K. Naviaux
Application Serial No.: 09/889,251
Filed: November 1, 2001
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PATENT
Attorney Docket No.: UCSD1140-1

REMARKS

A. Regarding the Amendments

Courtesies extended to Applicant's representative during the telephone interview on February 24, 2003 are acknowledged with appreciation. By the present communication, claims 1-6, 8-19, 25, 26, and 66 have been amended to more particularly define Applicant's invention. As amended, the claims are supported by the specification and the original claims and add no new matter. Claims 1-28 and 66 are under examination.

B. Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 4 and 5 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim subject matter which Applicant regards as the invention, is respectfully traversed. Present claims 4 and 5 have been amended and no longer recite the word "derivative". The Examiner's suggestion of acceptable alternative claim language is acknowledged with appreciation. It is respectfully submitted that the rejection does not apply to present claims 4 and 5. Accordingly, reconsideration and withdrawal of the rejection of claims 4 and 5 under 35 U.S.C. 112, second paragraph, are respectfully requested.

C. Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 1-28 and 66 under 35 U.S.C. § 112, first paragraph, as containing subject matter which is allegedly not described in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and or use the invention, is respectfully traversed. The present claims are drawn to methods of treating a specific, well-defined set of disorders, i.e., renal tubular acidosis (RTA); Leigh syndrome; MARIAHS syndrome; mitochondrial disease leading to stroke-like episodes; lactic acidemia; Pyruvate Dehydrogenase (PDH) deficiency; encephalomyopathy; ataxia and encephalopathy; cytochrome c oxidase (COX, Complex IV) deficiency; cardiomyopathy; Alzheimer's disease; and multiple mitochondrial deletion syndrome. It is respectfully submitted that the specification and the Declaration that accompanies this response describe in great detail methods for treating the claimed disorders.

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For example, pages 14 and 15 of the specification describe successful treatment of renal tubular acidosis according to the methods of the invention. Likewise, pages 15-17 describe in detail methods for treating MARIAHS syndrome. Indeed, each of the Examples in the specification describes treatment of disorders set forth in the present claims. In addition, the Declaration describes further examples of successful treatment of the claimed disorders according to the methods of the present invention. For example, in the Exhibit to the Declaration, Example 7 describes successful treatment of Pyruvate Dehydrogenase (PDH) deficiency, encephalopathy, and Leigh syndrome according to the methods of the invention. Similarly, Example 8 describes effective treatment of Alzheimer's disease.

Clearly, ample guidance is provided by the specification (and the accompanying Declaration) such that those skilled in the art would readily be able to practice the methods of the presently claimed invention without undue experimentation. Thus, it is respectfully submitted that the rejection under 35 U.S.C. § 112, first paragraph does not apply to present claims 1-28 and 66. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

D. Rejection Under 35 U.S.C. § 102

The rejections of claims 1, 7, 25, and 27 under 35 U.S.C. 102(b) as allegedly being anticipated by Isono, et. al., (Japanese Patent No. 53056690), claims 1-7 and 25-27 under 35 U.S.C. 102(e) as allegedly being anticipated by von Borstel, et. al. (U.S. Patent No. 6,258,795), claims 1-28 and 66 under 35 U.S.C. 102(a) as allegedly being anticipated by Naviaux, et. al. ("Mitochondrial Dysfunction in Human Pathology", meeting in Melbourne, Australia), and claims 1-28 and 66 under 35 U.S.C. 102(e) as allegedly being anticipated by von Borstel, et. al. (U.S. Patent No. 6,472,378), are respectfully traversed.

Applicant's invention, as defined for example, by claim 1, distinguishes over each of the cited references by requiring a method for the treatment of a disorder comprising administering to a subject having or at risk of having such disorder an effective amount of a well-defined pyrimidine-based nucleoside, wherein the disorder is selected from renal tubular acidosis (RTA);

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Leigh syndrome; MARIAHS syndrome; mitochondrial disease leading to stroke-like episodes; lactic acidemia; Pyruvate Dehydrogenase (PDH) deficiency; encephalomyopathy; ataxia and encephalopathy; cytochrome c oxidase (COX, Complex IV) deficiency; cardiomyopathy; Alzheimer's disease; multiple mitochondrial deletion syndrome, and any combination thereof. None of the cited references describe methods for treating the specific disorders set forth in claim 1. Thus, the references do not recite each and every element of the present claims. Accordingly, reconsideration and withdrawal of the rejection of claims 1-28 and 66 under 35 U.S.C. § 102(a), 102(b), and 102(e) are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge additional claim fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: April 3, 2003



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